REMARKS

This is in response to the Office Action mailed October 25, 2002. Claims 2 and 3 have been canceled. Claims 8, 9, 11 and 12 have been withdrawn. Claims 1, 4-7, and 10 have amended. New claims 13-42 are added. Claims 1, 4-7, 10, and 13-42 are now pending.

Support for the claim language as to the mutation sites in claim 1 as amended appears, for example, in Table 2. Support for the claim language as to the term "anti-HBV drug treatment" (e.g., lamivudine therapy) in independent claim 32 appears, for example, in the specification on page 31, line 31, and in Table 2.

Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. For the Examiner's convenience and reference, Applicants' remarks are presented in the order in which the corresponding issues were raised in the Office Action.

1. Description of Drawings in the Specification

The Examiner states that the description of Figure 1 does not describe part A and B separately.

In response, Applicants amend the specification to describe part A and B separately as Figure 1A and Figure 1B, respectively.

2. Information Disclosure Statement (IDS)

The Examiner states that the listing of references in the specification is not a proper information disclosure statement.

Applicants submit that the list of references in the end of the specification is provided to show the state of art at the time when patent application was filed. A separate IDS is submitted herewith.

3. Rejections under 35 U.S.C. § 112, Second Paragraph

The Examiner rejects claims 1-7, 10 under 35 U.S.C. § 112, Second Paragraph for being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, the Examiner rejects claims 1-5 for being indefinite as to the term "capable of hybridizing". Applicants amend independent claim 1 to recite that the first and second primers "hybridize" to regions of HBV, as suggested by the Examiner.

The Examiner further rejects claims 2-4 for being infinite as to the term "corresponding to" in claims 2 and 3. Applicants' cancellation of claims 2 and 3 renders the rejection moot.

The Examiner also rejects claim 10 for being indefinite as to the terms "<400>1" and "<400>2". Applicants amend claim 10 to recite the SEQ ID NOs comprised in the first primer and the second primer.

In view of the above amendments and remarks, the pending claims are sufficiently definite to one of ordinary skill in the art under 35 U.S.C. § 112, Second Paragraph. Withdrawal of the indefinite rejections is therefore respectfully requested.

4. Rejections under 35 U.S.C. § 102

1) Over Mbayed et al.

The Examiner rejects claims 1-3 and 10 under 35 U.S.C. § 102(b) as being anticipated by Mbayed et al. (J. Clinical Microbiology (1998) 36:3362-3365).

Independent claim 1 as amended specifies a primer extension amplification method for detecting mutation of HBV in a sample, including a mutation at amino acid position 130, 131, 133 or 145, or mutations at amino acid positions 130 and 145, 130 and 133, 131 and 145, or 133 and 145.

Mbayed et al. does not teach a method for detecting mutation at these specific amino acid positions. Thus, Mbayed et al. fails to anticipate the claimed invention. Withdrawal of the rejection under 35 U.S.C. § 102(b) is therefore respectively requested.

2) Over McDonough et al.

The Examiner rejects claims 1-3 and10 under 35 U.S.C. § 102(b) as being anticipated by McDonough et al. (US Patent No: 5,780,219).

As discussed above, independent claim 1 as amended specifies a primer extension amplification method for detecting mutation of HBV in a sample, including a mutation at amino

acid position 130, 131, 133 or 145, or mutations at amino acid positions 130 and 145, 130 and 133, 131 and 145, or 133 and 145.

McDonough et al. does not teach a method for detecting mutation at these specific amino acid positions. Thus, McDonough et al. fails to anticipate the claimed invention. Withdrawal of the rejection under 35 U.S.C. § 102(b) is therefore respectively requested.

3) Over Weinberger et al.

The Examiner rejects claims 1-3 under 35 U.S.C. § 102(b) as being anticipated by Weinberger et al. (Viral Hepatitis and Liver Disease, pp. 138-143, Torino, Edizioni Minerva Medica, 1997).

As discussed above, independent claim 1 as amended specifies a primer extension amplification method for detecting mutation of HBV in a sample, including a mutation at amino acid position 130, 131, 133 or 145, or mutations at amino acid positions 130 and 145, 130 and 133, 131 and 145, or 133 and 145.

Weinberger et al. does not teach a method for detecting mutation at these specific amino acid positions. Thus, Weinberger et al. fails to anticipate the claimed invention. Withdrawal of the rejection under 35 U.S.C. § 102(b) is therefore respectively requested.

5. Rejections under 35 U.S.C. § 103(a)

1) Over Mbayed et al.

The Examiner rejects claims 10 as being unpatentable over Mbayed et al. under 35 U.S.C. § 103(a).

As discussed above, independent claim 1 as amended specifies a primer extension amplification method for detecting mutation of HBV in a sample, including a mutation at amino acid position 130, 131, 133 or 145, or mutations at amino acid positions 130 and 145, 130 and 133, 131 and 145, or 133 and 145.

Mbayed et al. neither teaches nor suggests a method for detecting mutation at these specific amino acid positions. A prima facie case of obviousness has not been established under 35 U.S.C. § 103(a). Withdrawal of this ground of rejection is respectively requested.

2) Over Mbayed et al., McDonough et al. or Weinberger et al. in view of Mason et al.

The Examiner rejects claims 10 under 35 U.S.C. § 103(a) as being unpatentable over Mbayed et al., McDonough et al. or Weinberger et al. in view of Mason et al.

As discussed above, independent claim 1 as amended specifies a primer extension amplification method for detecting mutation of HBV in a sample, including a mutation at amino acid position 130, 131, 133 or 145, or mutations at amino acid positions 130 and 145, 130 and 133, 131 and 145, or 133 and 145.

None of the cited references, each alone or in combination, teaches or suggests a method for detecting mutation at these specific amino acid positions. A prima facie case of obviousness has not been established under 35 U.S.C. § 103(a). Withdrawal of this ground of rejection is respectively requested.

3) Over Mbayed et al., McDonough et al. or Weinberger et al. in view of Dattagupta

The Examiner rejects claims 10 under 35 U.S.C. § 103(a) as being unpatentable over Mbayed et al., McDonough et al. or Weinberger et al. in view of Dattagupta.

As discussed above, independent claim 1 as amended specifies a primer extension amplification method for detecting mutation of HBV in a sample, including a mutation at amino acid position 130, 131, 133 or 145, or mutations at amino acid positions 130 and 145, 130 and 133, 131 and 145, or 133 and 145.

None of the cited references, each alone or in combination, teaches or suggests a method for detecting mutation at these specific amino acid positions. A prima facie case of obviousness has not been established under 35 U.S.C. § 103(a). Withdrawal of this ground of rejection is respectively requested.

CONCLUSION

Applicants earnestly believes that they are entitled to a letters patent, and respectfully solicits Examiner to expedite prosecution of this patent application to issuance. Should Examiner have any questions, the Examiner is encouraged to telephone the undersigned.

Respectfully submitted,

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